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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,327	12/13/2001	Howard C. Krivan	44921-00005	4491

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BRUCE ROSE
LEGERE PHARMACEUTICALS, LTD.
3123 RESEARCH WAY
SUITE 215
CARSON CITY, NV 89706

EXAMINER

STEPHENS, JACQUELINE F

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 02/26/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,327

Applicant(s)

KRIVAN ET AL.

Examiner

Jacqueline F Stephens

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8 and 14-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8 and 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claims 3 and 16 are objected to because of the following informalities: the aforementioned claims recite the limitation "group consisting of WGA, SBA, ConA, and LCA". For the purpose of clarity, the lectins should be properly identified.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 14, 15, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Krivan et al. USPN 5217715.

As to claim 14, Krivan discloses a method of preventing toxic shock syndrome in humans caused by pathogenic microorganisms, which comprises administering to a human at least one lectin capable of diminishing the infective capability of the microorganism (col. 1, lines 54-57 and 67; col. 2, lines 16-43).

As to claim 15, Krivan discloses the microorganism is a strain of *Staphylococcus aureus* (col. 3, lines 15-17 and 40).

As to claim 19, Krivan discloses the composition has a pharmaceutically acceptable carrier (col. 2, lines 1-2).

Claim Rejections - 35 USC § 103

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oldham WO 95/09641.

As to claims 1 and 2, Oldham does not specifically disclose a method of coagulating menstrual flow with at least one lectin capable of agglutinating at least one of the constituents of menstrual flow. However, Oldham discloses lectins capable of agglutinating erythrocytes, which are known in the art as a component of red blood cells (page 6, lines 3-25). Oldham further discloses the lectins are capable of binding to vaginal tissue (page 11, lines 10-11), which may also comprise menstrual flow as a result of endometrial sloughing. Even though Oldham does not teach using the lectins

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to coagulate menstrual flow, the ability of the lectins to bond to pathogenic microorganisms in the vagina and treat vaginal infections (page 4, lines 26-29), render the lectins appropriate for use on a sanitary article, specifically a tampon, which can administer a medicament to the vaginal area. It would have been obvious to one having ordinary skill in the art to use the lectin to coagulate menstrual flow, as it provides the additional benefit of coagulating erythrocytes, which is a relatively large and insoluble material, that upon coagulation will also aid in the prevention of leakage of menstrual flow from the sanitary article.

As to claim 3, Oldham discloses lectins from the claimed group of substances (page 8, line 8 through page 9, line 32).

As to claim 4, Oldham discloses the lectin is administered vaginally (page 7, lines 30-35).

As to claim 5, Oldham discloses the lectin is in neat (without admixture) form (page 12, lines 30-32).

As to claim 6, Oldham discloses the lectin is contained in a vehicle (page 11, line 29 through page 12, line 12).

As to claim 8, Oldham discloses the lectin is contained in a non-absorbent device (thermoplastic film - page 13, line 6-11).

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6. Claims 14-19 are rejected under 35 U.S.C. 102(a) as being anticipated by Oldham WO 95/09641 in view of Jacob USPN 4722936.

As to claim 14, Oldham discloses a method of treating vaginal infections and for binding and immobilizing pathogenic microorganisms in the vagina (page 4, lines 25-28) by administering lectins to the vaginal area. Oldham discloses the microorganism is a strain of *Staphylococcus aureus* (page 10, lines 14-16). However, Oldham does not specifically disclose preventing toxic shock syndrome. Jacob discloses staphylococcus aureus is a bacterium that causes serious infection in humans and exists in most victims of Toxic Shock Syndrome (col. 2, lines 19-22). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the invention of Oldham in a manner of preventing Toxic Shock Syndrome, since the invention of Oldham is effective in immobilizing pathogenic microorganisms, like *Staphylococcus aureus*, which after entering the bloodstream elicits symptoms associated with Toxic Shock Syndrome (Jacob col. 2, lines 19-54 and Oldham page 11, lines 24-28).

As to claim 15, Oldham discloses the microorganism is a strain of *Staphylococcus aureus* (page 10, lines 14-16).

As to claim 16, Oldham discloses lectins from the claimed group of lectins (page 8, line 8 through page 9, line 32).

As to claim 17, Oldham discloses the lectin is administered vaginally (page 7, lines 30-35).

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As to claim 18, Oldham discloses the lectin is in neat (without admixture) form (page 12, lines 30-32).

As to claim 19, Oldham discloses the lectin is contained in a vehicle (page 11, line 29 through page 12, line 12).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline F Stephens whose telephone number is (703) 308-8320. The examiner can normally be reached on Monday-Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on (703)305-1025. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacqueline F Stephens
Examiner
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February 23, 2004